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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/035,708	03/05/98	ZEMLAN	F 1259-064

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HM12/0602

EXAMINER

DUFFY, P

ART UNIT	PAPER NUMBER
1645	6

DATE MAILED: 06/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/035,708

Applicant(s)

Zemlan et al.

Examiner

Duffy

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-30 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-30 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1645

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to anti-tau antibodies, classified in class 530, subclass 387.1.
 - II. Claims 4-9, drawn to fragments of tau protein, classified in class 530, subclass 350.
 - III. Claim 10, drawn to fragments of the light neurofilament subunit, classified in class 530, subclass 350.
 - IV. Claim 11, drawn to fragments of the medium neurofilament subunit, classified in class 530, subclass 350.
 - V. Claim 12, drawn to fragments of the heavy neurofilament subunit, classified in class 530, subclass 350.
 - VI. Claim 13, drawn to protein fragment of neurofilament 66, classified in class 530, subclass 350.
 - VII. Claims 14-30, drawn to method of detecting axonal damage by detection of an axonal derived protein, classified in class 435, subclass 7.1.
- Species A* - tau
- Species B* - light neurofilament subunit
- Species C* - medium neurofilament subunit
- Species D* - heavy neurofilament subunit
- Species E* - neurofilament 66.

Art Unit: 1645

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a materially different process of using such as administration in vivo for the diagnosis or used in a method of affinity purification of the protein of interest.

Inventions I and (II-VI) are related as protein products. The protein products are distinct each from the other because they have different primary protein sequences, have different structural characteristics, are differently located, and have different functions. In the instant case, the antibodies of Group I function to bind an antigen of interest to mediate immune reactions whereas the instantly claimed proteins (Groups II-VI) provide structural functions to the cells and are produced as a by product of axonal damage. Each of the proteins of group II-VI are distinct each from the other because they have different primary sequences, form different size neurofilament structures which are distinguished from each other based on the size and subunit composition.

Inventions II-VI and VII are not related. The protein fragments of groups II-VI are not required to practice the methods of detection of Group VII and thus are deemed distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

Art Unit: 1645

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-VI, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group VII-

Species A - tau

Species B - light neurofilament subunit

Species C - medium neurofilament subunit

Species D - heavy neurofilament subunit

Species E - neurofilament 66.

Each of the species is distinct each from the other because they have different primary sequences, form different size neurofilament structures which are distinguished from each other based on the size and subunit composition

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14, 15, 23, 26, and 30 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

Art Unit: 1645

of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Should applicant elect Group VII for prosecution, it is noted that the application was filed with duplicate page 27 and no page 28, and thus claim 30 is incomplete as written. Applicants' response should address the incomplete issue in regard to claim 30. Any additional claims will not be considered as originally filed.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Patricia A. Duffy, Ph.D.
June 1, 1999

Patricia A. Duffy
Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600